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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/588,192                       |             | Romed Meirer         | 69643.002200        | 6758             |
| 21967                            | 7590        | 05/25/2011           |                     |                  |
| HUNTON & WILLIAMS LLP            |             |                      | EXAMINER            |                  |
| INTELLECTUAL PROPERTY DEPARTMENT |             |                      | SANTOS, JOSEPH M    |                  |
| 1900 K STREET, N.W.              |             |                      |                     |                  |
| SUITE 1200                       |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20006-1109        |             |                      | 3737                |                  |
|                                  |             |                      |                     |                  |
|                                  |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                  |             |                      | 05/25/2011          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/588,192             | MEIRER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | JOSEPH M. SANTOS       | 3737                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 April 2011.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 34-56 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 34-56 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

***DETAILED ACTION***

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/08/2011 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **35, 37-39, 42-46, 48-56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 is indefinite because it doesn't properly limit the number of shock waves previously set forth; having "at least 500 impulses" imply that the number of impulses can be more than the maximum of 5000 impulses previously set forth. Claims 35, 38, 39, 42-43 are indefinite because they depend from a cancelled claim. Claims 35, 36, 38, 39, 42-43 are interpreted as depending from claim 34 for purpose of prior art rejection. Claims 48-50 refer to claim 46 rather than claim 47. Claim 48 is indefinite because it set forth focused shock waves, however claim 48 depends from claim 46, which further depends from claim 38 that sets forth unfocused shock waves. Claims 48, 49 appear to be redundant in view of claims 38 and 39 respectively. Claims 50-52 also appear to be redundant in view of the limitations of claim 34.

***Claim Rejections - 35 USC § 103***

Art Unit: 3737

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims **34-37, 39-48, 50-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over George et al (US 6,334,069) in view of Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia".

George et al discloses a method an apparatus for the treatment of chronic wounds on a patient's skin using pulsed electromagnetic (EM) energy. Such treatment provides healing treatment to burns and surgically implanted skin graft (see abstract, col. 10, lines 18-26). However, George et al fails to specifically teach to treat the skin using shock waves pulses provided by a shock wave applicator having the claimed number of pulses and energy flux density. In the same field of endeavor, Ogden et al. disclose a therapeutic device and method used to generate shock waves medical treatment of a variety of pathological conditions associated with bone environments and musculoskeletal environments; such shock waves induce soft tissue morphogens and growth factors (see col. 3, lines 17-44). Ogden et al further teach the number shock

wave pulses per treatment should be approximately 500-10,000 (see, col.6, lines 5-8). It would have been obvious to one skilled in the art to replace one type of wave (EM waves) for another (shock waves) to treat the skin in order to provide tissue angiogenesis in the grafted area. Such a modification involves the substitution of one known type of treatment wave for another in a process of treating skin grafts. The substitution of one known type of wave for another would have yielded predictable results to one skilled in the art at the time of the invention. However the modified George fails to teach having shock wave pulses at an energy flux density of from  $0.05\text{mJ/mm}^2$  to  $0.2\text{mJ/mm}^2$ . In the same field of endeavor Sanctis discloses a shock wave applicator applied to the skin having pulses with an energy flux density of  $0.03\text{mJ/mm}^2$  to  $0.5\text{mJ/mm}^2$  (See Abstract). It would have been obvious to have modified George to apply pulses with such a specific flux density in order to increase microcirculation. With respect to claims 37, 39, Ogden discloses applying focused shock waves (col. 3, lines 55-60). With respect to claims 40-46 and 53-56 the specific size of the area in which the shock wave is to be applied would have been obvious depending on the specific size of the wound.

5. Claims **38 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over George et al (US 6,334,069) in view of Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia", as applied to claims 37, 46 above and in further view of Applicant's admission of record. George discloses the systems and methods as disclosed above, but fails to specifically teach the shock waves include unfocused shock waves. However, in the applicant's specification is disclosed that the industry provides two main generation methods of extracorporeal shock waves focused and unfocused (see para. 0066, of applicant's specification). Therefore, having unfocused shock waves is well known expedient. It would have been obvious to have modified George to have unfocused shock waves signals in order to treat the wound with a desired shock wave.

***Response to Arguments***

6. Applicant's amendments to the claims and specification are sufficient to overcome the objection to the specification and the 35 USC 112, first paragraph rejection.
7. Applicant's arguments filed 04/08/2011 have been fully considered but they are moot in view of new grounds of rejection.
8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, both Ogden and Sanctis et al. are analogous prior art to the current invention; both disclose treatment of the body using acoustic shock waves. Therefore, Examiner maintains that the combination does sufficiently establish a prima facie case of obviousness.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH SANTOS whose telephone number is 571-270-7782. The examiner can normally be reached on Monday through Friday 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRIAN CASLER can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.S./  
Examiner, Art Unit 3737

/Ruth S Smith/  
Primary Examiner, Art Unit 3737